

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
ANDERSON DIVISION

UNITED STATES OF AMERICA, }
Plaintiff, } Case No. 8:13-cv-1675-JMC
v. }
860 cases more or less, of an article)
of food, labeled in part:)
(case))
"*** PART # *** Lot # *** Exp. Date)
*** 12-BT Per Case-90CT ***")
(bottle))
"*** USPlabs OxyELITE Pro® Super)
Thermogenic™ *** DIETARY SUPPLEMENT)
90 capsules *** Proprietary Blend ***)
1,3-Dimethylamylamine HCl, ***)
Manufactured for USPlabs, LLC (Dallas,)
TX 75220) ***")
and)
848 cases more or less, of an article)
of food, labeled in part:)
(case))
"*** PART # *** Lot # *** Exp. ***)
6-BT Per Case ***")
(bottle))
"*** USPlabs Jack3d™ *** DIETARY)
SUPPLEMENT *** 250g *** Proprietary)
Blend *** 1,3-Dimethylamylamine HCl,)
*** Manufactured for USPlabs, LLC)
(Dallas, Texas 75220) ***",)
and)

)
 all other articles of food labeled as)
 containing 1,3-Dimethylamylamine HCl)
 (DMAA) or its chemical equivalent in)
 various flavors, sizes, and forms and)
 various sized containers that are)
 located anywhere on the premises of)
 General Nutrition Centers, Inc., (GNC))
 or Nutra Manufacturing, 4941 Liberty)
 Highway, Anderson, South Carolina, to)
 which are affixed labels bearing,)
 among other things, the name and)
 address of the manufacturer identi-)
 fied as USPlabs, LLC, Dallas, Texas,)
 which is located outside the state of)
 South Carolina,)
)
 Defendants.)

VERIFIED COMPLAINT FOR FORFEITURE IN REM

NOW COMES the United States of America, William N. Nettles, United States Attorney for the District of South Carolina, Leesa Washington and George Conits, Assistant United States Attorneys, respectfully state as follows:

NATURE OF THE ACTION

1. That this complaint is filed by the United States of America, and requests seizure and condemnation of articles of food as described in the caption, in accordance with the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*

JURISDICTION AND VENUE

2. That this Court has jurisdiction over an action commenced by the United States under 28 U.S.C. § 1345 and 21 U.S.C. § 334.

3. That there is at Anderson, South Carolina, in the possession of General Nutrition Centers, Inc., (GNC), 4941 Liberty Highway, Anderson, South Carolina, or elsewhere within the jurisdiction of this Court, articles which are foods within the meaning of 21 U.S.C. § 321(ff), which

consist in whole or in part of ingredients that were shipped in interstate commerce from outside the state of South Carolina.

4. That this Court has *in rem* jurisdiction over the articles, because they are located in the District of South Carolina.

BASIS FOR FORFEITURE

5. That the articles of food are adulterated when received in interstate commerce and while held for sale, within the meaning of the Act, 21 U.S.C. 342(a)(2)(C)(i), in that they contain the food additive DMAA, which is unsafe within the meaning of 21 U.S.C. § 348.

6. That by reason of the foregoing, the articles are held illegally within the jurisdiction of this Court and are liable to seizure, condemnation, and forfeiture pursuant to 21 U.S.C. § 334.

FACTS

7. United States Food and Drug Administration (FDA) Investigators conducted an inspection of General Nutrition Centers, Inc., on May 29, 2013, thru June 6, 2013. During the inspection, the Investigators identified Jack3d™, and OxyElite Pro® Super Thermogenic™ as being labeled as containing 1,3-Dimethylamylamine HCl (DMAA). During the inspection, the Investigators collected physical samples, photographed product containers and cases, and collected interstate shipping records.

8. All articles of food located anywhere at General Nutrition Centers, Inc., labeled as containing the ingredient DMAA or its chemical equivalent, shipped from USPlabs, LLC in Dallas, TX to GNC, located in Anderson, South Carolina, are adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(i).

9. Under 21 U.S.C. § 321(s), a substance intended to become a component of

food is a food additive unless (1) it is generally recognized among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown to be safe under the conditions of its intended use; (2) it is subject to prior sanction; or (3) it is an ingredient described in 21 U.S.C. § 321(ff) (a dietary ingredient). The other exceptions listed in 21 U.S.C. § 321(s) do not apply.

10. DMAA is not a dietary ingredient, because it does not meet any of the elements of 21 U.S.C. § 321(ff)(1).

11. DMAA is not generally recognized as safe under the conditions of use in these products. DMAA does not satisfy the second exception because it is not the subject of a sanction or approval pursuant to the Act, or the other statutes identified in 21 U.S.C. § 321(s). DMAA is, therefore, a food additive.

12. Under 21 U.S.C. § 348(a), a food additive is deemed unsafe unless it is used in conformity with a regulation prescribing conditions under which it may be safely used, it has been granted an exemption for investigational use under 21 U.S.C. § 348(j), or it is a food contact substance. DMAA is not a food contact substance, there is no regulation prescribing the conditions under which DMAA may be safely used, and no exemption for investigational use has been granted under 21 U.S.C. § 348(j). Therefore, DMAA is deemed unsafe under 21 U.S.C. § 348 and, the defendant Articles containing DMAA are deemed adulterated under 21 U.S.C. § 342(a)(2)(C)(i).

13. By reason of the forgoing, the articles of food are held illegally within the jurisdiction of this Court and are liable to seizure and condemnation pursuant to 21 U.S.C. § 334.

14. WHEREFORE, the United States of America prays that:

- (a) a warrant of arrest issue for all articles of food as described in the caption that are located at General Nutrition Centers, Inc., Anderson, South Carolina;
- (b) condemnation and judgment be entered declaring the defendant articles of food be forfeited to the United States of America and grant plaintiff the costs of this proceeding against the claimant of the articles;
- (c) defendant articles be disposed of pursuant to the provisions of the Act;
- (d) and the United States of America be granted such other and further relief that the Court deems just and proper.

Respectfully submitted,
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